

CLAIMS

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al → 1. A collagen material which is filled or had inside
a substance having biocompatibility that can be degraded
5 and absorbed in the body into a matrix of a non-woven
fabric-like multi-element structure of collagen fibers
having ultra-fine fibers of collagen as its basic unit.

2. The collagen material according to claim 1,
10 wherein said substance having biocompatibility that can be
degraded and absorbed in the body and being filled into
said matrix is collagen fiber containing ultra-fine fibers
of collagen newly formed by performing a freezing and
freeze-drying procedure to a hydrochloric acid solution of
15 extracted collagen introduced into said matrix.

3. The collagen material according to claim 1,
wherein said substance having biocompatibility that can be
degraded and absorbed in the body and being contained
20 inside said matrix is selected from the group consisting of
polyglycolic acid, polylactic acid, copolymer of glycolic
acid and lactic acid, polydioxanone, copolymer of glycolic
acid and trimethylene carbonate, and a mixture of
polyglycolic acid and polylactic acid, and is used as a
25 mesh-like sheet or tube, or a non-woven fabric-like sheet
or tube.

4. The collagen material according to claims 2 or 3,
wherein said non-woven fabric-like multi-element structure
30 of collagen fiber is composed of that in which collagen
plate-like fibers having a diameter of 20-50 μm are
randomly intertwined, said plate-like fibers are composed
of that in which collagen fibers having a diameter of 5-8
 μm overlap in the coaxial direction, said fibers are

composed of that in which bundled rows of narrow collagen fibers having a diameter of 1-3 μm are alternately overlapping as warp and weft, said narrow fibers are composed of that in which fine collagen fibers having a diameter of 30-70 nm are bundled, and said fine fibers are composed of that in which ultra-fine collagen fibers having a diameter of 3-7 nm that are comprised of several collagen molecules are bundled.

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5. A collagen material in which a biocompatible substance that can be degraded and absorbed in the body is filled into a non-woven fabric-like matrix of a substance having biocompatibility that can be degraded and absorbed in the body.

6. The collagen material according to claim 5, wherein said substance having biocompatibility that can be degraded and absorbed in the body which composes said non-woven fabric-like matrix is selected from the group consisting of polyglycolic acid,, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate, and a mixture of polyglycolic acid and polylactic acid.

7. The collagen material according to claim 5, wherein said substance having biocompatibility that can be degraded and absorbed in the body and is filled into said matrix is amorphous collagen obtained by air-drying a hydrochloric acid solution of extracted collagen introduced into said matrix, or collagen fiber containing ultra-fine fibers of collagen newly formed by performing a freezing and freeze-drying procedure to said hydrochloric acid solution of extracted collagen introduced into said matrix.

8. The collagen material according to claim 7,
 wherein said collagen fibers are composed of that in which
 collagen plate-like fibers having a diameter of 20-50 μm
 are randomly intertwined, said plate-like fibers are
 5 composed of that in which collagen fibers having a diameter
 of 5-8 μm overlap in the coaxial direction, said fibers are
 composed of that in which bundled rows of narrow collagen
 fibers having a diameter of 1-3 μm are alternately
 overlapping as warp and weft, said narrow fibers are
 10 composed of that in which fine collagen fibers having a
 diameter of 30-70 nm are bundled, and said fine fibers are
 composed of that in which ultra-fine collagen fibers having
 a diameter of 3-7 nm that are comprised of several collagen
 molecules are bundled.

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9. The collagen material according to claims ~~2 or 4~~,
 wherein said collagen material has one-point support tensile
 force of at least 30 N and rupture resistance tensile force
 of at least 65 N in the dry state, and has one-point
 20 support tensile force of at least 1.4 N and rupture
 resistance tensile force of at least 6.5 N in the wet state
 (for a thickness of 1 mm)..

10. The collagen material according to any one of
 25 claims 3, ^{5, 7, or} ~~4 and 6 to 8~~, wherein said collagen material has
 one-point support tensile force of at least 10 N and
 rupture/resistance tensile force of at least 25 N in the
 dry state, and has one-point support tensile force of at
 least 5 N and rupture resistance tensile force of at least
 30 15 N in the wet state (for a thickness of 1 mm).

11. A production process of a collagen material
 comprising performing at least the steps indicated below in
 order:

a. a collagen solution layer is formed by casting a hydrochloric acid solution of extracted collagen to a desired thickness;

b. said collagen solution layer is temporarily frozen
5 and held in that state for a desired amount of time followed by freeze-drying;

c. thermal dehydration crosslinking is performed for a predetermined amount of time on said freeze-dried product;

10 d. said hydrochloric acid solution of extracted collagen is introduced into the matrix of said thermal dehydration crosslinked product;

e. the product introduced said solution of extracted collagen therein is temporarily frozen, held in that state
15 for a predetermined amount of time and then freeze-dried;

g. said freeze-dried product is compressed; and,

i. thermal dehydration crosslinking is performed for a predetermined amount of time on that compressed product.

20 12. The process according to claim 11, wherein the following steps are performed in order between said step e and step g:

f1. said hydrochloric acid solution of extracted collagen is again introduced in the matrix of said freeze-dried product; and,
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f2. the product introduced said extracted collagen solution therein is temporarily frozen, held in that state for a desired amount of time, and then freeze-dried.

30 13. The process according to claims 11 or 12, wherein the following step is performed between said steps g and i:

h1. a collagen solution layer is formed at a predetermined site on the surface of said compressed product.

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14. The process according to claim 13, wherein the following step is performed between said steps h1 and i:

h2. said collagen solution layer is compressed.

5 15. The process according to any one of claims 11 to 14, wherein the freezing and holding time during the freezing procedure in said steps b, e and f2 is 6-48 hours.

10 16. The process according to any one of claims 11 to 14, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen in said steps d and f1 is 0.5 wt% or less.

15 17. The process according to claims 13 or 14, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen for forming a collagen solution layer in said step h1 is 2.0 wt% or less.

20 18. The process according to claims 11 or 15, wherein casting of a hydrochloric acid solution of extracted collagen in said step a is divided into two procedures, and a mesh-like sheet or tube comprising a material selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, 25 polydioxanone, copolymer of glycolic acid and trimethylene carbonate and a mixture of polyglycolic acid and polylactic acid is contained between both collagen solution layers between both casting procedures, said step g is performed after said step c while said step i is not performed.

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19. The process according to claim 18, wherein the following steps are additionally performed after said step g:

35 h3. a collagen solution layer or gelatin gel layer is formed on at least one side of said compressed product; and,

h4. thermal dehydration crosslinking is performed on the product formed said collagen solution layer or said gelatin gel layer.

5 20. The process according to claim 19, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen for forming said collagen solution layer is 2 wt% or less.

10 21. The process according to claim 19, wherein said gelatin concentration of the gelatin aqueous solution for forming said gelatin gel layer is 5-25 wt%.

15 22. A production process of a collagen material comprising performing at least the following steps in order:

20 j. a hydrochloric acid solution of extracted collagen is introduced into a non-woven fabric-like sheet-like or tube-like matrix comprising a material selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate and a mixture of polyglycolic acid and polylactic acid, followed by air-drying;

25 l. a collagen solution layer is formed on at least one side of the product introduced and air-dried said hydrochloric acid solution of extracted collagen;

 o. a gelatin gel layer is formed on said collagen solution layer; and,

30 p. thermal dehydration crosslinking is performed on the product formed said gelatin gel layer for predetermined amount of time.

35 23. The process according to claim 22, wherein the following step k is performed between said steps j and l,

and the following step m is performed between said steps l and o:

k. the product introduced said extracted collagen is temporarily frozen, and that state is maintained for a predetermined amount of time followed by freeze-drying;

m1. the product on which said collagen solution layer is formed is temporarily frozen, and that state is maintained for a predetermined amount of time followed by freeze-drying; and,

m2. the product freeze-dried is compressed.

24. The process according to claims 22 or 23, wherein the following step n is performed between said steps l and o or between said steps m2 and o:

n. thermal dehydration crosslinking is performed for a predetermined amount of time on the product on which said collagen solution layer is formed or the product freeze-dried.

25. The process according to any one of claims 22 to 24, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen in said steps j and l is 2.0 wt% or less.

26. The process according to any one of claims 22 to 24, wherein the gelatin concentration of the gelatin aqueous solution in said step o is 5-25 wt%.

27. The process according to any one of claims 11 to 17, wherein the collagen material produced has one-point support tensile force of at least 30 N and rupture resistance tensile force of at least 65 N in the dry state, and one-point support tensile force of at least 1.4 N and rupture resistance tensile force of at least 6.5 N in the wet state (for a thickness of 1 mm).

28. The process according to any one of claims 18 to 26, wherein the collagen material produced has one-point support tensile force of at least 10 N and rupture resistance tensile force of at least 25 N in the dry state, and one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 25 N in the wet state (for a thickness of 1 mm).